

10/564096

Docket No. 282276US0PCT

IAP20163075770 11 JAN 2006

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Rosario LIZIO, et al.

SERIAL NO: New U.S. PCT Application Based on PCT/EP04/07882

GAU:

FILED: Herewith

EXAMINER:

FOR: MULTIPARTICLE PHARMACEUTICAL DOSAGE FORM CONTAINING A MUCOADHESIVELY FORMULATED PEPTIDE OR PROTEIN ACTIVE SUBSTANCES METHOD FOR PRODUCING SAID PHARMACEUTICAL DOSAGE FORM

## INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97

COMMISSIONER FOR PATENTS  
ALEXANDRIA, VIRGINIA 22313

SIR:

Applicant(s) wish to disclose the following information.

## REFERENCES

- ☒ The applicant(s) wish to make of record the references listed on the attached form PTO-1449. Copies of the listed references are attached, where required, as are either statements of relevancy or any readily available English translations of pertinent portions of any non-English language references.
- ☐ A check or credit card payment form is attached in the amount required under 37 CFR §1.17(p).

## RELATED CASES

- ☐ Attached is a list of applicant's pending application(s), published application(s) or issued patent(s) which may be related to the present application. In accordance with the waiver of 37 CFR 1.98 dated September 21, 2004, copies of the cited pending applications are not provided. Cited published and/or issued patents, if any, are listed on the attached PTO form 1449.
- ☐ A check or credit card payment form is attached in the amount required under 37 CFR §1.17(p).

## CERTIFICATION

- ☐ Each item of information contained in this information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
- ☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this statement.

## DEPOSIT ACCOUNT

- ☒ Please charge any additional fees for the papers being filed herewith and for which no check or credit card payment is enclosed herewith, or credit any overpayment to deposit account number 15-0030. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

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IAP20 Rec'd PCT/PTO 11 JAN 2006

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#### STATEMENT OF RELEVANCY

- 1) References AA, AO-AQ, AW-AZ have been cited in the International Search Report. Copies of these references are being submitted herewith only when not automatically provided by the International Searching Authority.
- 2) References \_\_\_\_\_ have been cited in the corresponding \_\_\_\_\_ Search Report. A copy of these references is being submitted herewith.
- 3) References AR-AV are discussed in the specification. A copy of these references is being submitted here with.
- 4) References \_\_\_\_\_ are additional prior art known to Applicant. A copy of these references is being submitted herewith.

Form PTO 1449 (Modified)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY DOCKET NO. 282276US0PCT		SERIAL NO. 101564096 New US PCT Application Based on PCT/EP04/07882	
LIST OF REFERENCES CITED BY APPLICANT				APPLICANT Rosario LIZIO, et al.			
FILING DATE Herewith				GROUP			
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE	
	AA	6 468 959	10/22/02	WUNDERLICH et al.			
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						
	AL						
	AM						
	AN						
FOREIGN PATENT DOCUMENTS							
	DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION			
				YES	NO		
	AO	95/18602	07/13/95	WO-		NO	
	AP	93/13753	07/22/93	WO (with English abstract & equivalent of EP 0621775)		NO	
	AQ	1 203 590	05/08/02	EP		NO	
	AR	100 24 451	11/29/01	DE		NO	
	AS	02/03955	01/17/02	WO		NO	
	AT	02/064148	08/22/02	WO		NO	
	AU	02/043767	06/06/02	WO		NO	
	AV	03/007913	01/30/03	WO		NO	
OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)							
	AW	TRENKTROG et al. "Enteric coated insulin pellets: development, drug release and in vivo evaluation", European Journal of Pharmaceutical Sciences, vol. 4, pages 323-329 1996					
	AX	TAKEUCHI et al. "Enteral Absorption of Insulin in Rats from Mucoadhesive Chitosan-Coated Liposomes", Pharmaceutical Research, vol. 13, no. 6, pages 896-901 1996					
	AY	DORKOOSH et al. "Peroral drug delivery systems for peptides and proteins", S.T.P. Pharma Sciences, vol. 12, no. 4, pages 213-221 2002					
	AZ	BERNKOP-SCHNUERCH. "The use of multifunctional polymers for non-invasive peptide and protein application", Exp. Opin. Ther. Patents, vol. 10, no. 9, pages 1357-1366 2000				<input type="checkbox"/> Additional References sheet(s) attached	
Examiner				Date Considered			
*Examiner: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							